DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Agfa HealthCare N.V.
% Ms. ShaeAnn Cavanagh
Regulatory Affairs Specialist NA
AGFA Healthcare
10 South Academy Street
GREENVILLE SC 29601

January 6, 2015

Re: K142316
Trade/Device Name: IMPAX Agility
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 12, 2014
Received: December 12, 2014

Dear Ms. Cavanagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142316

Device Name

IMPAX Agility

Indications for Use *(Describe)*

IMPAX Agility is a Picture Archiving and Communications System (PACS). It provides an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks. IMPAX Agility is intended to be used by trained healthcare professionals including, but not limited to physicians, radiologists, orthopaedic surgeons, cardiologists, mammographers, technologists, and clinicians for diagnosis and treatment planning using DICOM compliant medical images and other healthcare data.

MPR, MIP and 3D rendering functionality allows the user to view image data from perspectives different from that in which it was acquired. Other digital image processing functionality such as multi-scale window leveling and image registration can be used to enhance image viewing. Automatic spine labelling provides the capability to semi-automatically label vertebrae or disks.

As a comprehensive imaging suite, IMPAX Agility integrates with servers, archives, Radiology Information Systems (RIS), Hospital Information Systems (HIS), reporting and 3rd party applications for customer specific workflows.

Lossy compressed mammography images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA-cleared for mammographic use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
Agfa IMPAX Agility

Common Name: Picture Archiving and Communications System (PACS)
Classification Name: Radiological Image Processing System
Regulatory Classification: 21 CFR 892.2050
Product Code: LLZ
Proprietary Name: IMPAX Agility
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jodi Coleman, Prepared: August 18, 2014
Telephone: 519-746-6210 ext. 2485

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's IMPAX Agility software, a picture archiving and communications system. It is substantially equivalent to systems with Agfa's IMPAX Next Generation (K111945), Agfa's IMPAX Volume Viewing 3.0 (K133135), and Siemens' Syngo.via (K123920).

B. DEVICE DESCRIPTION

Agfa's IMPAX Agility system is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks.

The new device is substantially equivalent to the predicate devices (K111945, K133135, & K123920). It is a comprehensive PACS system that allows the user to view and manipulate 3D image data sets. The new device includes some of clinical tools of the predicate devices specifically the functionality to perform image registration, segmentation, and automatic spine labeling.

The image registration functionality allows comparison studies to be registered with active study data to align them for reading. Registration only works for volumetric CT and MR data.

Segmentation of volumetric datasets allows the automatic removal of bones and the CT table. Bone and table removal is only available for CT datasets. Users can also manually define parts of the volume which should be removed, as well as highlight certain structures in volumes.

Automatic spine labeling tools provide the ability to label the vertebrae or the intervertebral discs of the spine. Automatic spine labeling automatically calculates the position of the vertebrae or discs after the user selects and labels an initial starting point. The user is required to confirm the automatic placement of the labels.

Principles of operation and technological characteristics of the new and predicate devices are the

same. There is no change to the intended use of the device vs. the predicate devices. Laboratory data, stability and performance assessments, usability tests, and functionality evaluations conducted with qualified radiologists confirm that performance is equivalent to the predicates.

C. INDICATIONS FOR USE

IMPAX Agility is a Picture Archiving and Communications System (PACS). It provides an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks. IMPAX Agility is intended to be used by trained healthcare professionals including, but not limited to physicians, radiologists, orthopaedic surgeons, cardiologists, mammographers, technologists, and clinicians for diagnosis and treatment planning using DICOM compliant medical images and other healthcare data.

MPR, MIP and 3D rendering functionality allows the user to view image data from perspectives different from that in which it was acquired. Other digital image processing functionality such as multi-scale window leveling and image registration can be used to enhance image viewing. Automatic spine labelling provides the capability to semi-automatically label vertebrae or disks.

As a comprehensive imaging suite, IMPAX Agility integrates with servers, archives, Radiology Information Systems (RIS), Hospital Information Systems (HIS), reporting and 3rd party applications for customer specific workflows.

Lossy compressed mammography images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA-cleared for mammographic use.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's IMPAX Agility system has an Indications For Use statement virtually identical the predicate device (K111945) and similar to the predicate devices (K133135 & K123920). The statements have been combined and simplified. Intended uses are the same. The devices have the same technological characteristics.

IMPAX Agility Indications For Use is equivalent to the predicate IMPAX Next Generation (K111945). Indications For Use and intended uses are the same. Both devices are indicated for mammography use, are used to render 3D, MIP, & MPR images, and utilizes MUSICA image reprocessing. Both IMPAX Agility and predicate device, IMPAX Volume Viewing 3.0 (K133135) are used to render 3D images. Both include image registration and segmentation functionality; however, IMPAX Volume Viewing 3.0 (K133135) is not indicated for mammography and IMPAX Agility is not intended for the visualization and measurement of vessel features. Both IMPAX Agility and the predicate device, Syngo.via (K123920) can be used to perform automatic spine labeling. However, Syngo.via (K123920) is not indicated for mammography. Differences in devices do not alter the intended diagnostic effect.

The devices have the same technological characteristics. The new device and the predicate devices (K111945, K133135 & K123920) are picture archiving and communication systems (PACS), Product Code LLZ. Agfa's IMPAX Agility system is substantially equivalent to the

predicate devices (K11194, K133135 & K123920) in that it uses precisely the same technology to capture, display, and process medical data. Descriptive characteristics and performance data are adequate to ensure equivalence.

The only difference of the new device is in the addition of the automatic spine labeling, segmentation and image registration. There are no changes to the intended use/indications of the device. Differences in devices do not alter the intended therapeutic/diagnostic effect.

Performance data including stability and performance assessments, usability tests, and functionality evaluations by qualified radiologists are adequate to ensure equivalence.

Table 1 on the next page summarizes the similarities and differences between the new device and predicate devices.

Product Comparison Table				
	IMPAX Agility (New Device)	**Agfa IMPAX NG (PREDICATE-K111945)**	**Agfa IMPAX Volume Viewing 3.0 (PREDICATE-K133135)**	**Siemens' Syngo.via (PREDICATE-K123920)**
Communications	Same as predicates	DICOM	DICOM	DICOM
Orthopedic Use, Treatment planning	Same as K111945	√	-	-
Mammographic Use	Same as K111945	√	-	-
Operating System	Same as predicates	Windows Vista, Windows 7	Windows XP,Windows 2007, Windows 2008	Windows XP, Windows 7
Network Access	Same as predicates	√	√	√
Multiple displays	Same as predicates	√	√	√
Image Export	Same as K111945 & K133135	BMP, JPG, TIF, AVI	BMP, JPG, TIF, AVI	-
Window Level	Same as predicates	√	√	√
Multi-Scale Window Level	Same as K111945 & K123920	√	-	√
Pan/Zoom	Same as predicates	√	√	√
Rotate	Same as predicates	√	√	√
Calibrate/Measure	Same as predicates	√	√	√
Annotate	Same as predicates	√	√	√
MIP, MPR, 3D Rendering	Same as predicates	√	√	√
Musica Image Reprocessing	Same as K111945	√	-	-
Patient Information System (HIS/RIS)	Same as K111945	√	-	-
Dictation & Speech Recognition	Same as K111945	√	-	-
Automatic Spine Labeling	Same as K123920	-	-	√
Image Registration	Same as K133135	-	√	-
Segmentation tools, automatic table and bone removal	Same as K133135	-	√	-

Table 1: Device Predicate Comparison

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's IMPAX Agility system is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks.

It is a software device running on commercially available computer equipment that allows users to view and modify DICOM compliant medical images and patient information.

Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices. The new device includes some of the clinical tools of the predicate devices specifically the functionality to perform image registration, segmentation, and automatic spine labeling. There are no differences between the device and the predicates (K111945, K133135 & K123920) that impact safety and effectiveness.

F. TESTING

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols as used for Medical Image Management Devices" as part of verification and validation under design controls (according to 21 CFR 820.30).

No animal or clinical studies were performed in the development of the new device. No patient treatment was provided or withheld.

1. IMPAX Agility vs. Agfa IMPAX Volume Viewing (K133135) - Requirements & Performance of the registration and automated removal of bone-like structures of the predicate were evaluated:

   Segmentation functionality accuracy was validated as part of the filing for the predicate device IMPAX Volume Viewing 3.0 (K133135). This algorithm for segmentation was re-used in IMPAX Agility; therefore, it was determined that a simple regression test to confirm the algorithm was integrated correctly would be sufficient to confirm substantial equivalence. Regression testing for bone removal was performed by an Agfa HealthCare employee who is a qualified medical professional. The testing consisted of comparing the accuracy of segmentation bone removal in IMPAX Agility compared to the predicate device IMPAX Volume Viewing 3.0 (K133135). All results met acceptance criteria.

2. Automatic spine labeling and 3D registration validation was carried out by three medical professionals at Agfa's testing lab in Belgium. Users evaluated the performance of the device with anonymized studies under a number of relevant workflows. Validation activities did not involve any patient treatment.

   Objectives of the automatic spine labeling validation were to evaluate:

   - The accuracy of the semi-automatically placed spine labels
   - The requirement of the user to confirm the accuracy of the semi-automatically placed spine labels

   Objectives of the 3D registration validation were to evaluate:

- The registered viewport is able to be linked to the reference viewport
- The data in the registration viewport is reformatted in such a way that the orientation and position of both datasets are aligned and the number of slices in the registration viewport is equal to the number of slices within the reference viewport. Both datasets are linked for navigation, orientation, zoom and pan.

All results met acceptance criteria.

Laboratory data, stability and performance assessments, usability tests, and functionality evaluations conducted with qualified radiologists confirm that performance is equivalent to the predicates.

The product, manufacturing and development processes conform to product safety and medical imaging standards including:

G. PRODUCT STANDARD

- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM).

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

H. RISK ASSESSMENT AND MANAGEMENT SUMMARY

During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with a conventional PACS system previously released to the field.

For IMPAX Agility Image Area there are a total of 18 risks in the broadly acceptable region and 21 risks in the ALARP region with only two identified for this version. Zero risks were identified in the Not Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

The benefits of IMPAX Agility are:

- Image and information review capabilities are enhanced over what is offered by traditional film:
  - Immediate access to all available prior patient studies.
  - Time independent access to patient records and information.
  - Simultaneous access to multimodality, multi-departmental image review (a chest x-ray, an, MRI, and CT for example).
- Improved resource utilization of both equipment and staff.
  - Improved communication between local and geographically separated healthcare providers promoting collaborative care.
  - Authorized Users are able to share same patient record and contribute to that record.

- Distribution of clinical data either through digital access, distribution or hardcopy print.

The residual risk of each hazardous situation was analyzed and it was determined that the overall benefits to the patient outweigh the residual risks.

I. CONCLUSIONS

Agfa's IMPAX Agility system has an Indications For Use statement virtually identical the predicate device (K111945) and similar to the predicate devices (K133135 & K123920). The statements have been combined and simplified. Intended uses are the same. The devices have the same technological characteristics.

IMPAX Agility Indications For Use is equivalent to the predicate IMPAX Next Generation (K111945). Indications For Use and intended uses are the same. Both devices are indicated for mammography use, are used to render 3D, MIP, & MPR images, and utilizes MUSICA image reprocessing. Both IMPAX Agility and predicate device, IMPAX Volume Viewing 3.0 (K133135) are used to render 3D images. Both include image registration and segmentation functionality; however, IMPAX Volume Viewing 3.0 (K133135) is not indicated for mammography and IMPAX Agility is not intended for the visualization and measurement of vessel features. Both IMPAX Agility and the predicate device, Syngo.via (K123920) can be used to perform automatic spine labeling. However, Syngo.via (K123920) is not indicated for mammography. Differences in devices do not alter the intended diagnostic effect.

The modified device is similar to the predicate devices. It is a comprehensive PACS system that allows the user to view and manipulate 3D image data sets. This new version includes automatic spine labeling, segmentation and image registration. Differences in devices do not alter the intended diagnostic effect.

Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices.

Agfa's IMPAX Agility system is substantially equivalent to the predicate devices (K11194, K133135 & K123920) in that it uses precisely the same technology to capture, display, and process medical data. Descriptive characteristics and performance data are adequate to ensure equivalence.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.